AUG 2 5 2006

K062088
P1/4

Special 510(k) Notification: Device Summary

July 19, 2006

Submitter:

William Parsons, Official Correspondent
Diagnostic Monitoring Software
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Trade Name: Premier 11 Holter
Common Name: Holter Analyzer
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, ambulatory, with analysis algorithm, Medical magnetic tape recorder
Regulatory Class: II (two)
Product Code: MLO

Establishment Registration Number: 2028190
Owner/Operator Number: 9003252
Payment Identification Number: MD6026579-956733

Legally marketed devices to which S.E. is claimed:

The Premier 11 Holter system is essentially the same as the previously cleared K911615B Premier Holter system, except that (1) the software (other than the analysis) was changed to Windows, and (2) the Premier 11 accepts Holter recorded ECGs from both cassette Holter recorders and digital Holter recorders.

The analyzed data, the Full Disclosure print-outs, and the printed ECG strips are essentially the same, and function in the same manner as the below predicate devices. This modification of the submitted Premier 11 Holter system is substantially equivalent (SE) to the following legally marketed predicate devices that were cleared 510(k)s under 21 CFR 870.2800, Class II:

- Diagnostic Monitoring Software, Premier Holter system, K911615B.
- Brentwood Medical Technology, IQmark Digital Holter, K031466

Description

The Premier 11 Holter is a software program that analyzes recorded ambulatory ECG (Holter), then creates ECG print-outs and numerical reports based on the analyzed data. The ambulatory ECG, as well as pacemaker pulse data, is pre-recorded onto data storage mediums by Holter ECG recorders. The Premier 11 Holter software reads these raw data into standard PC computers, and then performs analysis to generate numerical reports.

The Premier 11 Holter software provides review and editing tools that allow trained medical personnel to review and edit the initial analysis of the recorded Holter ECG data. This data processing is performed on a standard PC computer, such as an XP Home or Professional operating platform.

The cardiac data that is processed by the Premier 11 Holter is both individual ECG waveforms and patterns of consecutive ECG waveforms. The Premier 11 Holter software does not provide diagnostic interpretation of the ECG data. Only the trained physician can provide such diagnosis. The cardiac data processed by the Premier 11 Holter is used by trained medical professionals to assist them to perform diagnosis on patients with various cardiac rhythm patterns.

The Premier 11 provides the standard Holter ECG processing features; such as individual ECG print-outs, Full Disclosure ECG print-outs, multi-channel morphology and ST analysis, heart rate analysis, manual markers for measuring the QRS width in both filtered and unfiltered modes, editing of arrhythmias, editing of ECG strips, editing of abnormal ECG events, selection of desired page prints for the Holter report, PageScanning of 100% of the 24-hour ECG, and storage of the Holter ECG file for future review of the data. These same functions are in both the predicate Premier Holter system cleared under K911615B and in this modified Premier 11 Holter software.

The printing of the data can be performed by either Laser or Inkjet type printers, and the printing can be done in either B&W or color. These same print functions are found in both the predicate Premier software (K911615B) and in this modified Premier 11 software.

In fact, the analysis algorithm is still in DOS, and is essentially the same as the K911615B Premier software. The same testing data bases are used for verification and validation that the analysis results are the same for the original K911615B software, as well as the present day Premier 11 software. These test results, using the same input data are available for FDA inspection from the Premier Holter (K911615B) in the mid-1990's to the present day verification tests of the modified Premier 11 Holter software.

The function and results of the Premier 11 Holter software versus the predicate cleared device are the same, except that the Premier 11 Holter software operates in

the Windows environment.

The other listed predicate device is the IQmark Digital Holter (K031466), Brentwood Medical Technology. The reason this is listed as a predicate device is because Diagnostic Monitoring Software sold a version of its Premier Holter software (K911615B) to Brentwood Medical Technology in the early 1990's, and thus the genesis of the IQmark Digital Holter software is the Premier Holter software.

Comparisons to the Sponsor's Predicate Devices:

The Premier 11 Holter software is substantially equivalent (SE) to the below devices.

Platform	Premier 11	Premier	IQmark
Predicate Device	No	Yes	Yes
Owner	DMS	DMS	Brentwood
510(k) Number		K911615B	K031466
Type	IBM PC AT Compatible	IBM PC AT Compatible	IBM PC AT Compatible
CPU	> 200 Mbz Pentium	> 200 Mbz Pentium	> 200 Mbz Pentium
Hard Disk	> 100 G Bytes	> 540 M Bytes	> 540 M Bytes
Data Acquisition			
ECG Channels	2 or 3	2 or 3	2 or 3
Resolution	8 bits	8 bits	8 bits
Sampling Frequency	128 to 512	128	128
Digital Input	Yes	Yes	Yes
Software			
Operating System:			
• Analysis	DOS	DOS	DOS
• Remainder	Windows XP	DOS	Windows

The only substantial difference in software was the evolutionary change from DOS to Windows, except the Holter analysis remained in DOS.

Fundamental Scientific Technology:

As described above, there is no fundamental change in the scientific technology from the predicate devices to this Special 510(k) submission of the Premier 11 software.

Also, the product modifications of the Premier 11, as compared to the predicate Premier device (K911615B), do not affect the safety or effectiveness of the device.

Intended Use of Device:

The "Intended Use" of the Premier 11 software is the same as the predicate devices. The intended use is for evaluation of the recorded ECG for patients who are subject to physician ordered Holter ECG monitoring environments; such as, palpitations, dizziness, chest pains, shortness of breath, pacemaker function, and drug therapy follow-up. The evaluation includes the standard Holter software measurements and reporting of arrhythmia, ST changes, R-R Variability, QRS interval changes, and heart rate trends. The PC computer-generated results do not contain diagnostic interpretation. The data can be edited, and only the qualified physicians are intended to review the ECG data and to make a diagnosis.

The Premier 11 Holter is intended to be used only by physicians, or on the order and supervision of a physician.

The intended use of the Premier 11 has not changed from the cleared device, the Premier Holter software (K911615B).

Indications for Use:

See Section 3 for a separate page description of the Indications for Use.

Indications for Use are as follows:

- Assessment of symptoms that may be related to Rhythm Disturbances of the heart in patients from pediatric to adult age; such as, palpitations.
- Assessment of risk in patients with or without symptoms of arrhythmia; such as, patients with symptomatic or asymptomatic idiopathic hypertrophic cardiomyopathy and postmyocardial infarction patients with left ventricular dysfunction.
- Assessment of efficacy of anti-arrhythmic therapy.
- Assessment of pacemaker function.
- Detection of transient ST Depression, or Prinzmetal ST Elevation.

The Indications for Use of the Premier 11 software has not changed from the cleared device, the Premier Holter software (K911615B).

Division of Cardiovascular Devices
7/19/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2006

Diagnostic Monitoring Software
c/o Mr. William Parsons
Official Correspondent
292 Kingsbury Grade, #32
Stateline, NV 89449

Re: K062088
Trade Name: Premier 11 Holter
Regulation Number: 21 CFR 807.2800
Regulation Name: Ambulatory Electrocardiograph with Analysis Algorithm
Regulatory Class: Class II (two)
Product Code: MLO
Dated: August 15, 2006
Received: August 15, 2006

Dear Mr. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062088

Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

The indications for use for 24-hour ambulatory ECG for this modified Premier 11 software and the listed predicate devices are for ECG evaluation of, but limited, to typical symptoms of chest pains, palpitations, dizziness, shortness of breath, and pacemaker. More specifically, indications for use include the following:

- Assessment of symptoms that may be related to rhythm disturbances of the heart in patients from pediatric to adult age; such as, palpitations.
- Assessment of risk in patients with or without symptoms or arrhythmia; such as, patients with symptomatic or asymptomatic idiopathic hypertrophic cardiomyopathy and postmyocardial infarction patients with left ventricular dysfunction.
- Assessment of efficacy of anti-arrhythmic therapy.
- Assessment of pacemaker function.
- Detection of transient ST Depression, as well as Prinzmetal ST Elevation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062088